

COMPRESSION EXPERIMENTS ON MOXIFLOXACIN HCl FORM A OF US20070072895

Compression experiment on the pure API

A 200 mg sample of Moxifloxacin HCl in crystalline form A, showing the PXRD diffractogram reproduced in Attachment 4 (sample 423), was grinded in an agate mortar and then introduced in a Graseby Specac sample press used for the preparation of IR tablets. The powder was then compacted at a pressure of 10 tons for 30 seconds, to obtain a tablet of pure material.

The tablet was then analysed by means of PXRD (Sample 423A). The results are shown in attachment 5.

RESULT: the crystalline form of the API constituting the tablet is still form A.

Reproduction of example 6 of US20070072895

The procedure reported in example 6 of US20070072895 was repeated three different times generating three identical tablets of formulate containing 200 mg of moxifloxacin HCl form A (Sample 425, showing a PXRD as reported in attachment 6), 200 mg of Avicel pH 112 and 5 mg of magnesium stearate.

The three tablets (Samples 425A, 425B and 425C) were analysed by means of PXRD, obtaining the diffractograms reported in attachment 7.

RESULT: the crystalline form of moxifloxacin HCl contained in the tablets is form A.

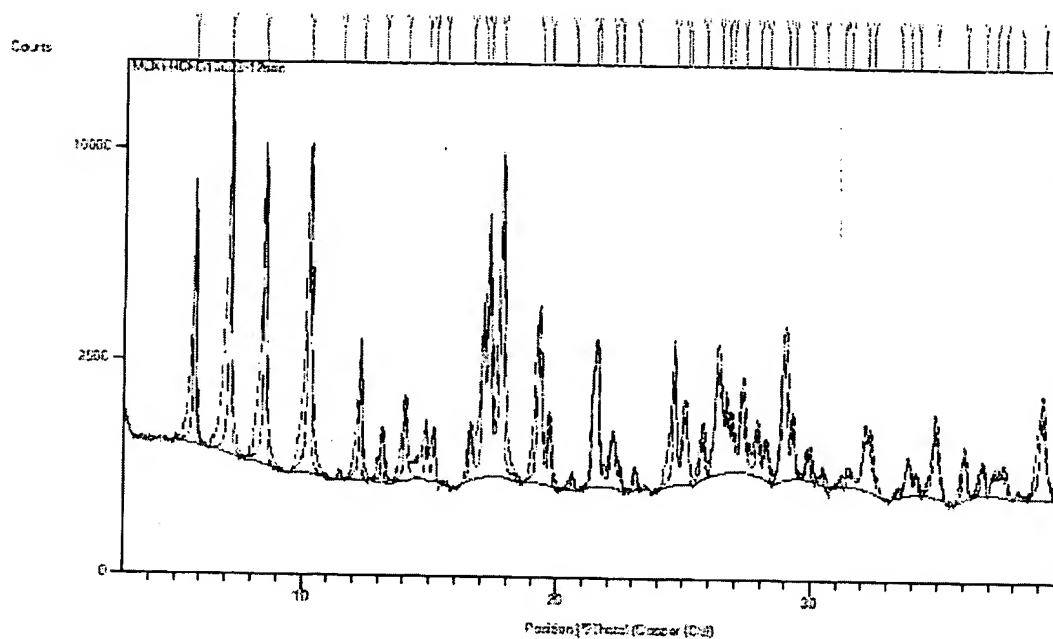
Patrica, June 15th 2009

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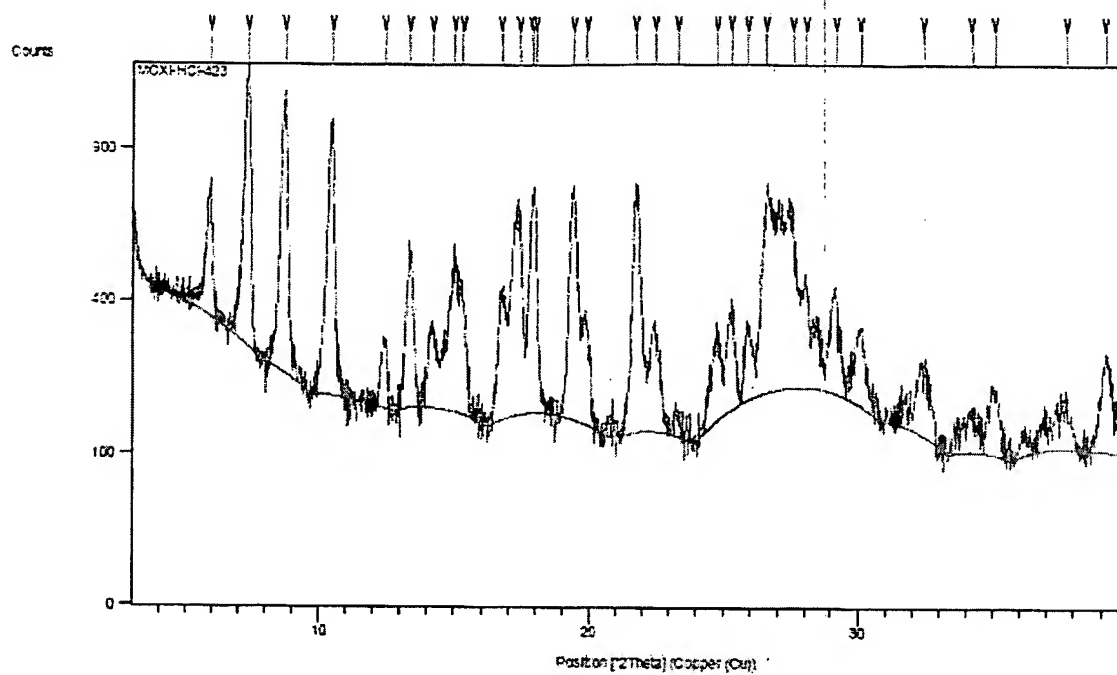
ATTACHMENT 4

PXRD of sample 423



ATTACHMENT 5

PXRD of sample 423A



ATTACHMENT 7

PXRD of sample 425A, 425B and 425C in comparison with original Chemi Form A

